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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,933	11/01/2001	Jeong S. Lee	ACSC 60355 (2750)	5440

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11/03/2005

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EXAMINER

MCKANE, ELIZABETH L

ART UNIT

PAPER NUMBER

1744

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/002,933

Applicant(s)

LEE ET AL.

Examiner

Leigh McKane

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-20, 27-32 and 35-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14-20 is/are allowed.
- 6) ☒ Claim(s) 27-32 and 35-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 27-30 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. (U.S. Patent No. 5,849,846).

Claims 27-30 and 38 are product-by-process claims. The process used to produce the product does not limit the product. Chen et al. teaches dilation catheters comprising an elongated shaft (tubing) and a balloon mounted on a distal end of the shaft (col.1, lines 24-27) wherein the catheters have a wall thickness of 0.00135 in (0.034 mm) and burst pressures after irradiation of 17-20 atm. See col.9, lines 34-45; col.11, lines 43-46. Thus the product of Chen et al., although produced by a different method, anticipates the product produced by the method of the instant claims.

3. Claims 27-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (WO 99/13924).

Claims 27-38 are product-by-process claims. The process used to produce the product does not limit the product. Lee et al. teaches PEBAX dilation catheters comprising an elongated shaft and a balloon mounted on a distal end of the shaft. See Abstract; page 4, lines 14-16. The catheters have a wall thickness of about 0.102 to 0.0381 mm (page 10, lines 5-6) and burst pressures of “about 16-21 ATM” (page 9, lines 3-4). Moreover, Lee et al. teaches a stent

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mounted on the balloon which may be metallic. See page 10, lines 11-18. Thus the product of Lee et al., although produced by a different method, anticipates the product produced by the method of the instant claims.

Allowable Subject Matter

4. Claims 14-20 are allowed.

5. The following is an examiner's statement of reasons for allowance: While Chen et al. does address rupture pressure and fatigue resistance, it is clearly taught by Chen et al. that the purpose of the irradiation is to *increase* the rupture pressure and fatigue resistance of the catheter balloon. See Chen et al., col.9, lines 21-45; col.10, lines 9-12. Thus, even when combined with Sun et al. so that oxygen is removed from the catheter during irradiation, the prior art of record fails to teach or suggest a method of sterilization wherein the rupture pressure or fatigue resistance after sterilization (irradiation) is less than or equal to the rupture pressure before sterilization.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Response to Arguments

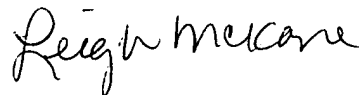
6. Applicant's arguments with respect to claims 27-32 and 35-38 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Thursday (5:30 am-2:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**Leigh McKane
Primary Examiner
Art Unit 1744**

elm
2 November 2005